American Orthotic & Prosthetic Association

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March 3, 2000

Dockets Management Branch, HFA-305
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20857

CITIZEN PETITION

The American Orthotic and Prosthetic Association submits this petition under section 513 of the Medical Device Amendments of 1976 (Public Law 94-295) [the amendments] to the Federal Food Drug, and Cosmetic Act [the act] (21 U.S.C. 360 c), as further amended by the Safe Medical Devices Act of 1990 (Public Law 101-629) and the Food and Drug Administration Modernization Act of 1997 to request the Commissioner of Food and Drugs to classify the "cranial helmet," an orthotic device used to provide protection for patients' skulls following cranial surgery and for skull protection in general.

A. ACTION REQUESTED

1. We respectfully request the Commissioner to classify the "Cranial Helmet," a previously unclassified device. We further request that this device be classified in Class I, exempt from premarket notification--510(k) requirements.

(a) Identification: Cranial Helmet

Examples of this device are shown in Attachment I, which contains copies of the cover of the American Orthotic and Prosthetic Association publication, *The Illustrated Guide to Orthotics and Prosthetics*, to show "Orthotic and Prosthetic Codes" in accordance with the Health Care Financing Administration "Common Procedure Coding System," and of page 1, which shows two examples of the "Helmet."

00P-1085

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1650 King Street, Suite 500, Alexandria, Virginia 22314, Phone 703.836.7116, Fax 703.836.0838, Http://www.aopanet.org

Under Code L0100 Cervical, craniostenosis, helmet molded to patient model, the device is described, "Plastic device molded over model of patient's head to provide protection after surgery or for a congenital defect." Under Code L0110 Cervical craniostenosis, helmet, non-molded," the device is described, "A protective helmet made with inner protective foam padding."

In the process of classifying the "cranial orthosis" under Section 207, Evaluation of automatic class III designation, of the FDA Modernization Act of 1997, the "Cranial Helmet" was recognized by the FDA as a preamendments but unclassified device. The examples show a chin-strap to hold the helmet in place. With modern plastic materials, the helmet can be formed to clasp the head firmly without need of a chin strap thus improving safety and comfort.

(b) Classification: Unclassified, preamendments

(c) Indications for use: Protection of the cranium (skull). A common use for this helmet is to protect the skull after surgery to reverse or ameliorate premature synostosis in infants. If uncorrected, this results in a badly deformed skull for the child. The helmet can also be used at the discretion of the physician to protect the skull after any type of cranial surgery and for skull protection in patients suffering from uncontrollable movement as sometimes observed with cerebral palsy.

(d) Structure: Helmets have been marketed for many years in various shapes and forms. Generally, they have appeared similar to old-fashioned aviator or football helmets--hence the commonly used name, "helmet". They uniformly have soft protective interiors of biocompatible, readily-cleaned or sanitized materials. Modern materials include polyurethane foams. Frequently, this soft-padded interior is covered with a harder material to provide protection if the helmet is bumped against solid objects and to hold the designed shape of the helmet. This covering material is semi-rigid polyethylene, polyvinyl chloride, styrene or other similar material.

2. The action requested of the Commissioner is to publish a document in the proper form providing classification of this orthotic medical device. We believe a logical classification would be in CFR 890, Physical Medicine devices, where most other low-risk orthoses are classified. Another possibility is CFR 880 General Hospital and Personal Use Devices. We also request that this old, very low risk device should be placed in Class I and made exempt from premarket notification requirements like most other low-risk orthoses.

B. STATEMENT OF GROUNDS

Experience in applying the Medical Device Amendments to the regulation of orthotic and prosthetic devices shows that the device as described above should be classified with other low-risk orthotic devices.

Only one cranial orthotic device has been classified to date. This is the "Cranial Orthosis", classified as a Neurological Device in CFR 882.5970. This device was placed in Class II, with several special controls to insure that it was safe and effective for its intended use, "to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and or shape in infants from 3 to 18 months of age, with moderate to sever nonsynostotic positional plagiocephaly..." These controls were applied to minimize health risks FDA identified in their May 29, 1998 letter to Cranial Technologies, Inc. (Attachment II). These health risks were: (a) skin irritation, skin breakdown, and subsequent infection due to excessive pressure on the skin; (b) head and neck trauma due to alteration of the function center of mass of the head and the additional weight of the device; (c) impairment of brain growth and development from mechanical restriction of cranial growth; (d) asphyxiation due to mechanical failure, poor fit, and/or excessive weight that alters the infant's ability to lift the head, (e) eye trauma due to mechanical failure, poor construction and/or inappropriate fit, and (f) contact dermatitis due to the materials used in the construction of the device.

We believe the cranial orthosis described in CFR 882.5970 was classified in Neurological devices because of FDA's concern about possible effects on brain and cranial nerve development because of possible constriction

on an infant's growing skull. However, the "cranial helmet" is used for entirely different purposes. It is a simple helmet designed to protect the cranium of patients that have undergone extensive cranial surgery or that are subject to spastic or uncontrollable movements due to certain diseases (e.g. cerebral palsy). Unlike the cranial orthosis, the helmet is **not** designed to place pressure on the cranium. It does **not** apply pressure on prominent areas of the skull. Rather, the helmet is basically a specialized **wound bandage.** Some of these have not yet been finally classified but many of those that have, such as the elastic bandage (CFR 880.5075), and the liquid bandage (CFR 880.5090) are Class I, exempt from 510(k) requirements as are the limb orthosis (CFR 890.3475); truncal orthosis (CFR 890.3490) and many other related devices.

Most if not all of the concerns that FDA expressed about the Cranial Orthosis used for plagiocephaly do not apply to the Cranial Helmet. We will discuss these in order:

(a) skin irritation and breakdown due to excessive pressure on the skin. The Helmet does not apply excessive, or even limited pressure--it is designed for protection only.
(b) head and neck trauma due to...additional weight of the device. The Helmet is constructed of light materials and doesn't require the strength or rigidity needed to "guide" a developing young head. Also, it commonly covers more of the skull so that the center of gravity is not so markedly changed as with the cranial orthosis.
(c) impairment of brain growth and development from mechanical restriction of cranial growth. The helmet is carefully designed and constructed so that it **does not** restrict cranial growth in any way. Hence, neurological concerns are not pertinent to the helmet.
(d) asphyxiation due to mechanical failure, poor fit, and/or excessive weight that alters the infant's ability to lift the head. Because the helmet is not designed to be restrictive in any way, mechanical failure, poor fit and excessive weight are not pertinent to the helmet.
(e) eye trauma due to mechanical failure. Again, the helmet has no "mechanical" purpose other than protection so this also is not a concern with a properly designed helmet.
(f) contact dermatitis due to the materials used in the construction of the device. The helmet fits much more loosely and thus dermatitis and skin

problems are less. In addition, the helmet was identified as a preamendment (pre-1976) device during classification of the "cranial orthosis". During this extended period of usage, the knowledge of biocompatibility of materials has advanced markedly. The "helmet" is constructed of materials that have been well established as biocompatible. Such materials are widely available and widely used in the industry for this and related uses. For example, the Class I, exempt "Truncal orthosis" includes many orthoses that are in close and continuous contact with the skin.

We believe our request is reasonable in view of the guiding principles of the FDA Modernization Act that devices be subjected to risk-based classification and placed in the lowest classification justified by any risk they pose to human health. The safety and effectiveness of this device in use is further assured because it is used under the close supervision of the physician treating the patient.

C. ENVIRONMENTAL IMPACT STATEMENT.

We submit that under 21 CFR 25.24(e)(2) this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

D. ECONOMIC IMPACT STATEMENT

The only economic impact of granting our petition would be to remove the need for some paperwork by small manufacturers and orthotists and to clarify and simplify the classification of these types of devices. Therefore, any impacts would be favorable to the industry. Exemption of this device from premarket notification requirements would slightly decrease regulatory overhead, permitting a slightly lower cost, favorable to consumers. The requested classification would relieve manufacturers of the device of the cost of complying with premarket notification requirements and may permit small potential competitors to enter the market place by lowering their costs.

In accordance with economic impact analytical requirements, this action would not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act. In accordance with section 3(g)(1) of Executive order 12291, the impact of this declassification has been analyzed and we are convinced the FDA will determine that the rule does not constitute a major rule as defined in section 1(b) of the Executive Order.

As stated in a recent classification document (FR 48439, Nov. 20, 1990, Vol. 55, No. 224, "In sum, device classification rules do not have a significant impact on a substantial number of small entities and are not major rules."

The undersigned, representing the American Orthotic and Prosthetic Association, a trade association representing the members of this vital industry, certifies that to the best of his knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

C. Michael Schuch

(Signature)
C. Michael Schuch, CPO, FISPO, FAAOP
President

ATTACHMENTS

I. Health care financing administration Common Procedure Coding System (HCPCS), "Orthotics and Prosthetics Codes," October 1985, American Orthotic and Prosthetic Association, Alexandria, Virginia.

II. Letter, Susan Alpert to Timothy Littlefield, Cranial Technologies, Inc., "Evaluation of Automatic Class III Designation--Dynamic Orthotic Cranioplasty - DOC™ Band, K964992, 4 pp. May 29, 1998.

HCPCS

Health care financing administration
Common **P**rocedure **C**oding **S**ystem

ORTHOTICS and PROSTHETICS CODES

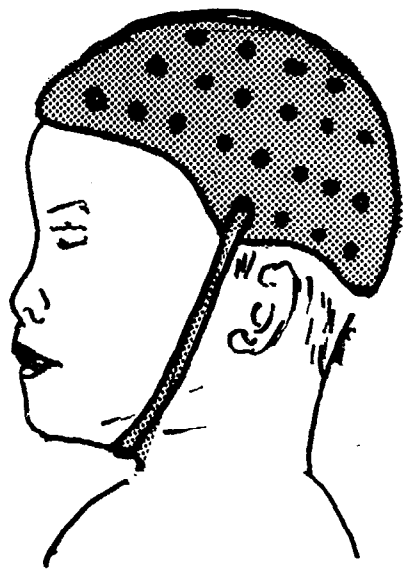
ATTACHMENT I

american
orthotic &
prosthetic
association

OCTOBER, 1985

L0100-L0209 Spinal-Cervical

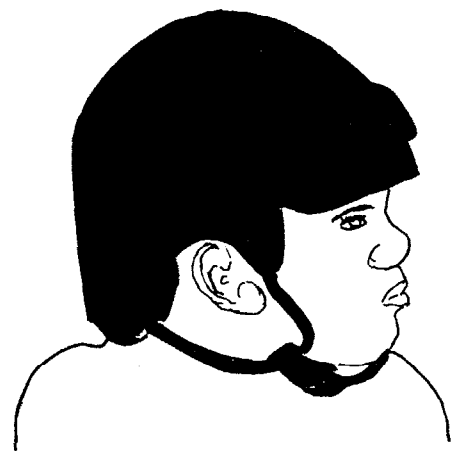
L0100 Cervical, craniostenosis, helmet molded to patient model



Plastic device molded over model of patient's head to provide protection after surgery or for a congenital defect.

Spinal-Cervical

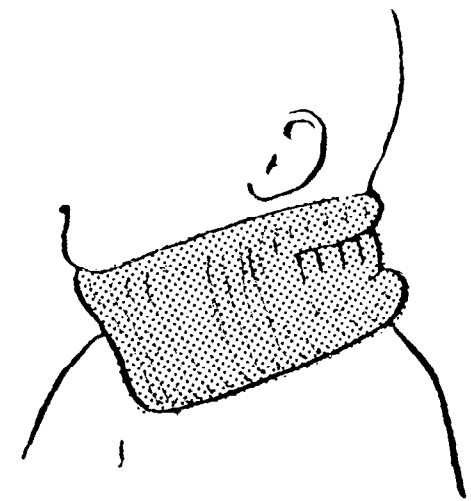
L0110 Cervical, craniostenosis, helmet, non-molded



A protective helmet made with inner protective foam padding.

Spinal-Cervical

L0120 Cervical, flexible, non-adjustable (foam collar)



A flexible foam support, usually covered with a woven material.

ATTACHMENT II

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 29 1998

Mr. Timothy R. Littlefield
Director, Research and Development
Cranial Technologies, Inc.
1331 North 7th Street, Suite 170
Phoenix, Arizona 85006

Re: Evaluation of Automatic Class III Designation - Dynamic Orthotic Cranioplasty - DOC™ Band - K964992
Dated: Undated
Received: March 31, 1998

Dear Mr. Littlefield,

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your petition, submitted in accordance with section 513(f)(2) of the Food, Drug, and Cosmetic Act, for classification of the Dynamic Orthotic Cranioplasty - DOC™ Band that is intended for use on infants from three to eighteen months of age with moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads. The device is intended to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape. FDA concludes that this device, and substantially equivalent devices of this generic type, should be classified into class II. This order, therefore, classifies the Dynamic Orthotic Cranioplasty - DOC™ Band, and substantially equivalent devices of this generic type into class II under the generic name, cranial orthosis. This order also identifies the special controls applicable to this device.

FDA identifies this generic type of device as a neurology device under 21 CFR 882.5970, as a cranial orthosis which is a device intended for medical purposes to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape. It is used to treat infants from three to eighteen months of age, with moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads.

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the act), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket

approval, unless and until the device is classified or reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the FDA regulations (21 CFR 807).

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) for a device may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1), request FDA to classify the device under the criteria set forth in section 513(a)(1). FDA shall, within 60 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** classifying the device.

In accordance with section 513(f)(1) of the act, FDA issued an order on March 12, 1998, automatically classifying the Dynamic Orthotic Cranioplasty - DOC™ Band in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, which was subsequently reclassified into class I or class II. On March 31, 1998, FDA filed your petition requesting classification of the Dynamic Orthotic Cranioplasty - DOC™ Band into class II. The petition was submitted under section 513(f)(2) of the act. In order to classify the Dynamic Orthotic Cranioplasty - DOC™ Band into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

After review of the information submitted in the petition and in the medical literature, FDA has determined that the Dynamic Orthotic Cranioplasty - DOC™ Band, intended for use in infants from three to eighteen months of age with moderate to severe non-synostotic positional plagiocephaly, including infants with plagiocephalic-, brachycephalic-, and scaphocephalic-shaped heads, to apply pressure to prominent regions of an infant's cranium in order to improve cranial symmetry and/or shape, can be classified in class II with the establishment of special controls. FDA believes that class II special controls provide reasonable assurance of the safety and effectiveness of the device.

FDA has identified the following risks to health associated with this type of device: (a) skin irritation, skin breakdown and subsequent infection due to excessive pressure on the skin; (b) head and neck trauma due to alteration of the functional center of mass of the head and the additional weight of the device especially with an infant who is still developing the ability to control his/her head and neck movements; (c) impairment of brain growth and development from mechanical restriction of cranial growth; (d) asphyxiation due to mechanical failure, poor

fit, and/or excessive weight that alters the infant's ability to lift the head; (e) eye trauma due to mechanical failure, poor construction and/or inappropriate fit; (f) contact dermatitis due to the materials used in the construction of the device.

In addition to the general controls of the act, the Dynamic Orthotic Cranioplasty - DOC™ Band is subject to the following special controls in order to provide reasonable assurance of the safety and effectiveness: (1) The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109. (2) The labeling must include (a) contraindications for the use of the device on infants with synostosis or with hydrocephalus; (b) warnings indicating the need: (i) to evaluate head circumference measurements and neurological status at intervals appropriate to the infant's age and rate of head growth, and to describe steps that should be taken in order to reduce the potential for restriction of cranial growth and possible impairment of brain growth and development; (ii) to evaluate the skin at frequent intervals, e.g., every three to four hours, and to describe steps that should be taken if skin irritation or breakdown occurs; (c) precautions indicating the need: (i) to additionally treat torticollis, if the positional plagiocephaly is associated with torticollis; (ii) to evaluate device fit and to describe the steps that should be taken in order to reduce the potential for restriction of cranial growth, possible impairment of brain growth and development and skin irritation and/or breakdown; (iii) to evaluate the structural integrity of the device and to describe the steps that should be taken to reduce the potential for the device to slip out of place and cause asphyxiation or trauma to the eyes or skin; (d) adverse events, i.e., skin irritation and breakdown that have occurred with the use of this device; (e) clinician's instructions for casting the infant, for fitting the device, and for care and use of the device; and (f) parents' instructions for care and use of the device. (3) The materials must be assessed for biocompatibility with testing appropriate for long term direct skin contact.

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, the device is not exempt from the premarket notification requirements. Thus, persons who intend to market this device must submit to FDA a premarket notification prior to marketing the device.
A notice announcing this classification order will be published in the **Federal Register**. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

FDA also requests that you submit final labeling to us as soon as possible and before commercial distribution of your device. If you have any questions concerning this classification order, please contact Mr. James Dillard, Deputy Director, Division of General and Restorative Devices, at (301) 594-1184.

Sincerely yours,

Susan Alpert, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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